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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,084	12/03/2003	Wade E. Keller	RADNT-013C2	6046

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EXAMINER

GIBSON, ROY DEAN

ART UNIT PAPER NUMBER

3739

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 10/727,084	Applicant(s) KELLER ET AL.	
	Examiner Roy D. Gibson	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-20 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-7,9-13,16 and 19 is/are rejected.
- 7) ☐ Claim(s) 14,15,17,18,20 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Entry of Amendment

Applicant's amendment filed on Sep. 20, 2005 is acknowledged. Claims 1-7, 9-21 and 39 are currently pending.

Prior Rejections or Objections

The following comments pertain to the rejections or objections in the most recent Office action mailed on March 16, 2005. Rejections under Double Patenting and 35 U.S.C. 102 are withdrawn, however, new grounds of rejection are presented below.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the temporary attachment of the looped tubular members to the guidewire (claim 20) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Note: the Specification should also be amended to include the element number newly assigned to the drawing.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

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and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 recites the limitation "the guidewire lumen" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al. (6,450,990).

As to claims 1-4, 6 and 10, Walker et al. disclose a heat exchange catheter comprising:

a longitudinal catheter shaft (302) having a proximal end and a distal end, an inflow lumen (Figure 3, # 304) and an outflow lumen (area between tubes 304 and 302);

a heat exchange region comprising a plurality of heat exchange elements (308), said heat exchange elements comprising looped tubular members (hollow fibers or single lumen tubes or hollow filaments # 310) which extend from the distal end of the catheter shaft and having first ends connected to the inflow lumen and second ends connected to the outflow lumen such that heat exchange fluid may be infused in a distal direction through the inflow lumen, through the looped tubular members and then in a proximal direction through the outflow lumen, substantial portions of said looped tubular members being unattached to the catheter shaft (col. 7, line 62-col. 8, line 67).

Further to claim 3, the some hollow fibers would inherently have a non-circular cross-section if they were not fully expanded by the pressure of the circulating fluid.

As to claim 5, Walker et al. further disclose the first and second ends of the looped tubular members are attached to the catheter shaft and the remainders of the looped tubular members float freely when the catheter is in use (Figure 3).

As to claims 7 and 9, Walker et al. further disclose the catheter includes an inlet manifold (Figure 3A) that receives heat exchange fluid from the inflow lumen, the first ends of the looped tubular members being connected to the inflow manifold such that heat exchange fluid flows from the inflow manifold into the looped tubular members and an outlet manifold (common with the inlet manifold and Figure 3A) connected to the outflow lumen and the second ends of the looped tubular members such that heat exchange fluid flows out of the second ends of the looped tubular members, through the outflow manifold and into the outflow lumen; wherein the looped tubular members comprise elongate hollow filaments having open first and second ends defining the respective inflow and outflow orifices, and wherein the inflow orifices communicate with the inflow manifold and the outflow orifices communicate with the outflow manifold (col. 8, lines 32-67).

Claim Rejections - 35 USC § 103

Claims 11-13, 16 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. in view of Johnson et al. (4,860,744). Walker et al. lack the disclosure of a tubular sleeve advanceable over the looped tubular members or that the catheter comprises a guidewire lumen and a guidewire. But, Johnson et al discloses a catheter for a controlled heat application with a sleeve (3) and a guidewire (2) and associated lumen (see col. 6, line 67-col. 7, line 11).

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Further to claims 13 and 16, Johnson et al. disclose an insulating region on the shaft (balloon or balloons 16) which is located partially proximally with respect to the heat exchange region (col. 7, lines 12-32).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Walker et al. as taught by Johnson et al. to provide a sleeve and guidewire to assist on positioning the catheter at the treatment site and an insulating balloon(s) to insulate the catheter shaft from the vessel wall to prevent over heating.

Allowable Subject Matter

Claims 14, 15, 17, 18, 20 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

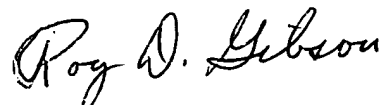
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Roy D. Gibson
Primary Examiner
Art Unit 3739

December 12, 2005